UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LINDA EVANGELISTA,	:	Civil Action No. 1:21-cv-7889
Plaintiff,	:	
-against-	:	**DEFENDANT ZELTIQ AESTHETICS, INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS**
ZELTIQ AESTHETICS, INC.,	:	
Defendant.	:	

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

ARGUMENT

I. Plaintiff pleaded time-barred claims (counts 1 through 10).

Plaintiff's brief both introduces unpleaded evidence about tolling agreements (which Zeltiq's opening brief candidly disclosed) and confirms that "[b]ecause the Complaint does not allege the existence of the . . . tolling agreement[s] nor incorporate [them] by reference, this Court is unable to consider that agreement in ruling on Defendant's motion to dismiss." *Bill Diodato Photography LLC v. Abon Prods., Inc.*, 2012 WL 3240428, at *4 (S.D.N.Y. Aug. 7, 2012) (cited in Plaintiff's Opposition Brief ("Opp. Br.") at 3 n.1, ECF No. 30). Rather than throwing stones for what she thinks Zeltiq should have known she was relying on that appears nowhere in her complaint, plaintiff should amend her complaint in response to this Court's dismissal to plead *all* the facts necessary to support her claims (if she can), including their timeliness. Zeltiq will respond to those facts, if pleaded in an again-amended complaint, as appropriate.

II. Counts 1 and 3 through 10 are warnings claims. They fail.

Plaintiff does not dispute that counts 3 through 10 are repackaged failure-to-warn claims. Zeltiq's Opening Brief ("Opening Br.") at 9 & n.4. All those claims allege Zeltiq gave inadequate PAH warnings for its prescription-only, FDA-cleared medical device, thereby causing plaintiff's injury. The learned intermediary doctrine applies to such claims—no matter how they are labeled—and disposes of plaintiff's consumer-based failure-to-warn claims. And plaintiff has not plausibly alleged that Zeltiq failed to warn her medical provider about PAH.[1]

[1] Plaintiff quotes the long-overruled pleading standard that "[d]ismissal is inappropriate unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him or her to relief." Opp. Br. at 2 (quoting *Sweet v. Sheahan*, 235 F.3d 80, 83 (2d Cir. 2000)). The Supreme Court has instructed that this "'no set of facts' language has been questioned, criticized, and explained away long enough"; it "has earned its retirement" in favor of the more strenuous "plausibility" standard announced in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007).

A. Zeltiq's duty to warn of medical risks runs to plaintiff's physician.

1. The learned intermediary doctrine applies under New York law.

Plaintiff's brief fundamentally misapprehends the learned intermediary doctrine. The learned intermediary doctrine is never an "absolute defense" or a "shield." Opp. Br. at 10–11. Rather, it is a doctrine that defines the scope of a medical-device manufacturer's duty to warn. The doctrine identifies *to whom* a medical-device manufacturer owes a duty to warn—to healthcare providers, not to patients. This is settled New York law. *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999) ("The learned intermediary doctrine focuses on the scope of a drug manufacturer's duty to warn of the dangers of using the drug in question."). The adequacy of the warning is then determined considering the recipient's (healthcare providers') common knowledge. *See* 21 C.F.R. § 801.109(c).

Plaintiff's argument that the learned intermediary doctrine only "applies" if a manufacturer provides adequate warnings is therefore wrong and unworkable.[2] Adequacy of a warning cannot be determined before defining to whom the duty runs. Only after the duty is defined (by application of the learned intermediary doctrine) can it be determined whether Zeltiq met its duty in providing an adequate warning to the physician. *See Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 285 (S.D.N.Y. 2009).

Plaintiff makes two familiar arguments why the learned intermediary doctrine should not apply here. First, she argues that CoolSculpting is "an elective, cosmetic procedure" that "does not require a physician to administer it," and that therefore the "nature of the relationship between plaintiff" and her physician is "at issue." Opp. Br. at 10–11. Second, she argues that

[2] *See, e.g.*, *Shahbaz v. Johnson & Johnson*, 2020 WL 5894590, at *14 (C.D. Cal. July 31, 2020) (explaining that even when a plaintiff *proves* that warnings were inadequate, the learned intermediary doctrine still applies).

"targeted and strategic direct-to-consumer advertising" negates the learned intermediary doctrine. *Id.* at 11–13. Neither argument has merit.

First, like all prescription devices, federal law restricts CoolSculpting's use to only "under the supervision of a practitioner licensed by law to direct the use of such device." 21 C.F.R. § 801.109; *see Fane v. Zimmer, Inc.*, 927 F.2d 124, 129 (2d Cir. 1991) (relying on 21 C.F.R. § 801.109 and applying learned intermediary doctrine in medical device case). Accordingly, CoolSculpting's User Manual, which accompanies the device, explicitly instructs that CoolSculpting is "RX ONLY" and only "intended for use by a trained physician or a physician-designated medical professional." User Manual at 3–4, ECF No. 26-2, pp. 18–19 of 86. Unsurprisingly, therefore, plaintiff pleads she "requested [CoolSculpting] treatment" *from her physician.* Am. Compl. ¶ 73. Plaintiff pleads no facts plausibly suggesting that, in light of all this, she could have treated herself with CoolSculpting or obtained treatment without her physician's knowledge and approval. Plaintiff thus pleads no factual basis why the learned intermediary doctrine does not apply to CoolSculpting.

Plaintiff ignores the wealth of New York case law applying the learned intermediary doctrine to prescription medical devices and cites a single case, *Bukowski v. CooperVision, Inc.*, 592 N.Y.S.2d 807 (N.Y. App. Div. 1993), in which the court "[could] not determine" the relationship between an optometrist and a contact-lens wearer in 1984. The court therefore declined to decide whether the learned intermediary doctrine applied. *Id.* at 807, 809. Many subsequent cases routinely apply the learned intermediary doctrine when it is clear and uncontested—as here—that the device at issue is available by prescription only through a licensed healthcare provider. *See, e.g.*, *Tomaselli v. Zimmer Inc.*, 2017 WL 2820065, at *4 (S.D.N.Y. Jan. 20, 2017) ("For medical devices that require a prescription . . . the duty to warn

runs to the prescribing physician, not the patient."); *Zottola v. Eisai Inc.*, -- F. Supp. 3d --, 2021 WL 4460563, at *5 (S.D.N.Y. Sept. 29, 2021) (applying doctrine over plaintiff's arguments that a prescription weight-loss drug was a "non-lifesaving medication" and was "more akin to a consumer product").

Second, direct-to-consumer (DTC) advertising does not alter application of the learned intermediary doctrine. Plaintiff says the out-of-state *Perez* case adopting a DTC exception to the learned intermediary doctrine "is instructive" (Opp. Br. at 12); it is not. What is instructive is that other states' courts reject *Perez* as an extreme outlier. *E.g.*, *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) ("Five years have passed since the New Jersey Supreme Court decided *Perez*. In the intervening period, no other state has followed New Jersey's lead."); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (same); *Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 950–51 (Ariz. 2016) ("[W]e decline to recognize a DTC advertising exception, which has been adopted only in New Jersey."). It is also instructive that this court has already predicted New York law would not recognize a DTC exception. *DiBartolo v. Abbott Laboratories*, 914 F. Supp. 2d 601, 615 (S.D.N.Y. 2012) (declining to find that "New York courts would apply a DTC exception"; "[c]ontrary to plaintiff's suggestion, moreover, there is no trend in favor of recognizing a DTC exception"). Plaintiff has not established, and cannot, that New York courts would adopt a DTC exception to the learned intermediary doctrine. She offers no reason for this Court to buck the overwhelming trend of rejecting that exception. Her consumer-based failure-to-warn claims must be dismissed.

2. The imposition of a duty to warn patients is preempted by federal law.

Other than saying she "does not ask the Court to impose any state law duty to warn" consumers directly about CoolSculpting (Opp. Br. at 13 n.3)—when her consumer-based failure-to-warn claims plainly do just that—plaintiff has no answer to Zeltiq demonstrating that such a

consumer-based, state-law duty is expressly preempted by federal law. Opening Br. at 13–14. The FDA has expressly declared that Zeltiq must provide medical warnings only to medical professionals and is "exempt from having adequate directions for lay use." FDA Special Controls at 7, ECF No. 26-2, p. 12 of 86. And the FDA has expressly declared that this has preemptive effect. 76 Fed. Reg. 6551-01, 6553 (Feb. 7, 2011). Imposing a state-law duty on Zeltiq to warn consumers directly about CoolSculpting's medical risks, as plaintiff asks the Court to do, is expressly preempted by federal law.

B. Plaintiff does not plausibly allege that Zeltiq failed to warn her physician.

Plaintiff makes vague and conclusory criticisms of Zeltiq's PAH warnings: they are "nondescript," "inaccurate," and "ambiguous"; they lack "the requisite specificity"; and they fail to use specific words that plaintiff thinks they should have used ("deformity" and "disfigurement"). *See* Opp. Br. at 7. And she contends that Zeltiq failed to disclose every bit of information it knew about PAH. *Id.*[3] But "[i]t has long been the law in New York that prescription [product] warnings are adequate when . . . information regarding 'the precise malady incurred' was communicated in the prescribing information." *Alston*, 670 F. Supp. 2d at 284. Zeltiq's User Manual warns of the "precise malady" of PAH using virtually the same language plaintiff uses to describe it in her complaint:[4]

[3] At the same point in her brief, plaintiff says Zeltiq's warning was also inaccurate because "Zeltiq . . . had information regarding the [PAH] . . . occurrence rate, which it did not disclose." Opp. Br. at 7. But later she says she "nowhere contends that Zeltiq is required to provide a specific numerical frequency rate of PAH to satisfy its duty to warn" (*id.* at 9 n.2), so apparently she has abandoned that argument. In any event, she does not dispute that, based on the details from her own complaint, Zeltiq's description of PAH as a "rare" adverse event is accurate. *See* Opening Br. at 16 & n.10.

[4] Plaintiff implies, but does not assert, that her own physician may not have relied on or had access to the User Manual that accompanies the device. Opp. Br. at 8. But in her complaint, she criticizes the Manual's warnings and alleges that "ZELTIQ knew . . . that providers and/or consumers . . . would rely upon the information it disseminated in its user manuals." Am. Compl. ¶ 313; *see id.* ¶¶ 269, 305-07, 333 (referencing User Manual).

Plaintiff's Amended Complaint (at p. 1), ECF No. 17	**CoolSculpting User Manual (at p. 4), ECF No. 26-2, p. 19 of 86**
"[P]aradoxical adipose hyperplasia [is] a serious adverse effect where the targeted fat cells increase in number and size (and actually grow larger) after treatment and form hard, bulging masses under the skin [that] requires invasive, corrective liposuction surgery to remove . . . ."	Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required.

This is the same basis on which another federal court relied to hold that Zeltiq's PAH warning is adequate as a matter of law:

> [T]here was nothing inaccurate or misleading about Defendant's warning that PH was a rare side effect causing visibly enlarged tissue volume that does not go away on its own and may require surgical intervention. Accordingly, Defendant's warnings to CoolSculpting providers (*i.e.*, learned intermediaries) were adequate as a matter of law.

Cates v. Zeltiq Aesthetics, 535 F. Supp. 3d 1222, 1229 (M.D. Fla. 2021), *appeal filed*, No. 21-12085 (11th Cir.). Plaintiff pleads nothing to distinguish this result. The Court should follow it.[5]

III. If reached, counts 4, 6, 7, 8, 9 and 10 independently fail.

If the Court holds that plaintiff fails to state a claim based on inadequate warnings, it need not reach these claims independently. But if it does, the claims still fail.

A. Plaintiff fails to state an express-warranty claim (count 4).

Plaintiff pleads two specific statements in her Amended Complaint that are supposedly express warranties: (1) that CoolScuplting "is safe and effective," and (2) that CoolSculpting treatment involves "No surgery. No downtime. Unmistakable results." *See* Am. Compl. ¶ 214. Her opposition brief confirms she has failed to state a claim for breach of express warranty based

[5] If the Court were to find that some of plaintiff's stated grounds for alleging Zeltiq's warning to be insufficient cannot support a viable claim, but that others can, then Zeltiq respectfully suggests that the Court specify that in its ruling. If, as just one example, the Court were to agree that plaintiff failed adequately to plead that Zeltiq's warning is insufficient because it describes PAH as "rare" (*see* Opening Br. at 16 & n. 10), but still found that plaintiff had managed to state a claim for failure to warn on some other basis, a clear ruling from the Court that the "rare" allegations do not survive this motion could significantly streamline the scope and expense of both fact and expert discovery and ultimately narrow the issues the Court would later have to confront at summary judgment.

on these two statements.

First, these statements do not qualify as express warranties under New York law. *See Krulewich v. Covidien LP*, 498 F. Supp. 3d 566, 578–79 (S.D.N.Y. 2020) ("safe and effective" is not "definite enough for a claim for breach of express warranty"); *Viania v. Zimmer, Inc.*, 2017 WL 5714725, at *5 (E.D.N.Y. Nov. 27, 2017) (same); *Dunham v. Covidien, LP*, 498 F. Supp. 3d 549, 561 (S.D.N.Y. 2020) (even statement comparing a device's "fibrous ingrowth" was "vague" and not an express warranty).

Second, plaintiff does not plausibly plead that she relied on these alleged warranties, for two reasons. One reason is that, while her brief cites the paragraphs in her complaint that identify Zeltiq statements containing these alleged warranties (Opp. Br. at 14–15), it does not and cannot cure her failure to plead which of those statements she actually saw, read, or heard, and under what circumstances. She pleads vaguely that she "learned about the CoolSculpting System from ZELTIQ's direct-to-consumer advertisements, ZELTIQ's promotional materials, and socially among her friends." Am. Compl. ¶ 68; c*f. Koublani v. Cochlear Ltd.*, 2021 WL 2577068, at *15 (E.D.N.Y. June 23, 2021) ("Without the 'when, where, and how' leading to [plaintiff's] reliance . . . an express-warranty claim is too conclusory to pass muster under Rule 12(b)(6)."). The other reason is that she fails to meaningfully address her signed informed consent form that she pleads in her Amended Complaint. She argues that Zeltiq is not a party to that document and so cannot invoke it. Opp. Br. at 16. But Zeltiq does not make a legal argument that requires any degree of legal standing regarding that document. It makes only a simple factual point under Rule 12(b)(6): plaintiff cannot plausibly plead that she relied on alleged warranties from Zeltiq that her CoolSculpting treatment was completely safe from any risk, complication, or side effect, when she affirmatively pleads that, before receiving treatment

(Am. Compl. ¶ 81), she was informed of and acknowledged there were "possible risks and complications" from "known side effects" including, specifically, her "fat growing instead of going away," which "may require surgical correction." Informed Consent at 000015, ECF No. 26-2, p. 86 of 86.

Third, plaintiff pleads no plausible breach. That plaintiff allegedly experienced PAH after CoolSculpting treatment does not imply that the device is *not* safe and effective. *See In re Avandia*, 588 F. App'x 171, 176 (3d Cr. 2014) ("safe and effective" "cannot be read as an unqualified guarantee that [the drug] would be safe and effective for all consumers"); *Otero v. Zeltiq Aesthetics, Inc.*, 2018 WL 3012942, at *3 (C.D. Cal. June 11, 2018) ("[T]he [FDA]'s classification of a device as Class II does indicate that certain 'special controls' provide 'reasonable assurance of the safety and effectiveness of the device[.]" (quoting 21 U.S.C. § 360c(a)(1)(B)). Plaintiff does not allege that Zeltiq failed to adhere to the FDA's Special Controls or general controls, which the FDA states "will be sufficient to provide reasonable assurance of the safety and effectiveness of" CoolSculpting. FDA Special Controls at 1, ECF No. 26-2, p. 6 of 68; *see Ortiz v. Allergan, Inc.*, 2015 WL 5178402, at *5 (S.D.N.Y. Sept. 4, 2015) (rejecting express-warranty claim regarding "safe and effective" where "[p]laintiff failed to provide factual allegations supporting her claim that the [d]efendant failed to comply with FDA requirements"). Nor does plaintiff allege that her *CoolSculpting procedure itself* involved surgery or downtime—which is all that Zeltiq was referring to in the other statement she alleges is a warranty. *See* Am. Compl. ¶ 24 ("*the CoolSculpting procedure* requires no surgery or downtime" (emphasis added)).

B. Plaintiff fails to state any fraud claim (counts 6 through 9).

Plaintiff's argument to try to save her fraud claims has the same problem as her express-warranty argument. To be sure, plaintiff's complaint pleads, and her brief re-references, a long

list of alleged Zeltiq statements. Opp. Br. at 17–18. But it is not enough for her to plead what Zeltiq said; she must also plead with particularity what she saw, read, or heard and relied on. For this, her brief does nothing but repeat the only vague and conclusory allegation on this point from the Amended Complaint: plaintiff "learned about CoolSculpting, in part, from Zeltiq's direct-to-consumer advertising, promotional materials, website and social media." Opp. Br. at 19 (citing Am. Compl. ¶ 68). But which ones? The ones made only *after* she completed her CoolSculpting treatment? The ones she alleges were made only to physicians and not to consumers like herself? Or ones that she did see but refuses to specify? Courts regularly dismiss fraud claims that contain this same type of pleading failure. *See* Opening Br. at 20–22.

C. Plaintiff fails to state a claim under N.Y. Gen. Bus. Law §§ 349 and 350.

Plaintiff uses two cases to argue that Zeltiq's statements about its prescription-only FDA-cleared medical device are consumer-oriented conduct under N.Y. Gen. Bus. Law §§ 349 and 350. First, plaintiff cites *Mahoney v. Endo Health Solutions, Inc.*, 2016 WL 3951185 (S.D.N.Y. July 20, 2016). There, the court allowed claims under §§ 349 and 350 to proceed in a children's multivitamin case where "[t]he labels and inserts," which contained the relevant warnings, "were directed towards pharmacists and consumers." *Mahoney*, 2016 WL 3951185, at *1–2, *9. Second, plaintiff cites *Williamson v. Stryker Corp.*, 2013 WL 3833081 (S.D.N.Y. July 23, 2013). There, the plaintiff had direct conversations with the knee-implant manufacturer's employees, present at the surgery, who told plaintiff that the device had *never* failed. *Williamson*, 2013 WL 3833081, at *1–2, *14. Neither case helps plaintiff.

Here, by contrast, Zeltiq's alleged statements are about its prescription CoolSculpting medical device, which consumers cannot buy and use on their own, and plaintiff alleges no idiosyncratic, point-of-treatment personal discussion she had with any Zeltiq representative. The more applicable case to cite is *Zottola*, which held that "Plaintiff has not adequately alleged that

Defendants engaged in 'consumer-oriented' conduct . . . because, 'the generally alleged deceptive practice of failing to provide adequate warnings [for a medical product] by concealing information is, as a matter of law, not a practice directed at consumers.'" *Zottola*, 2021 WL 4460563, at *4 (quoting *Wholey v. Amgen.*, 86 N.Y.S.3d 16, 17–18 (App. Div. 2018)). Rather, "[i]t was the duty of doctors—not Defendants—to disclose the [prescription medical product's safety] risks to patients, i.e., consumers. Accordingly, and as a matter of law, Defendants' alleged deception by failing to disclose [those] risks was not 'consumer-oriented' conduct." *Id.*[6]

Finally, these claims have the same fault as other claims: she fails to adequately plead what the alleged materially deceptive act is because she fails to plead which alleged statement her claim is based on. Her brief is correct when it says "[s]he describes the content of various television, video, and print ads in or around Ms. Evangelista's first treatments as well as a Facebook page where Zeltiq directly communicates with consumers." Opp. Br. at 22. But once again she fails to plead what content from which of those various materials she ever saw herself, if any. *Quintana v. B. Braun Med.*, 2018 WL 3559091, at *10 (S.D.N.Y. July 24, 2018) ("These allegations do not suggest Plaintiff ever saw these statements and under what circumstances."); *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 901 (E.D.N.Y. 2018) ("None of these allegations provides any indication that Plaintiff ever saw these statements and, to the extent he did, where, when and how Plaintiff came to view either the website or the product brochure.").

* * *

For the reasons articulated, the Court should dismiss counts 1through 10 of the Amended Complaint.

[6] Indeed, even the DTC Zeltiq advertisements like the 2015 "Fear No Mirror" ad linked in plaintiff's Amended Complaint (¶ 58) end with, "As with any medical procedure, only your physician can help you decide if CoolSculpting is right for you."

Dated: February 1, 2022

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of February 2022, a true and correct copy of the foregoing was filed through the Court's CM/ECF case management system, which will send a notice of electronic filing to all counsel of record.

s/ Alyson B. Jones
Attorney